File No.: 16051-9US CC/DBB/jrl

July 23, 2007 Montréal, Canada

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Andrew Vaillant et al.

**ASSIGNEE:** 

REPLICOR INC.

**SERIAL NUMBER:** 

10/661,088

TITLE:

ANTIVIRAL OLIGONUCLEOTIDES TARGETING HBV

FILING DATE:

September 12, 2003

ART UNIT:

1648

**EXAMINER:** 

PENG, Bo

# <u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 CFR § 1.97(d)</u>

Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450 Sir:

Submitted herewith on a PTO/SB/08A form is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR § 1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §§ 1.97(d).

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR § 1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is

### Serial No. 10/661,088

determined to be a *prima facie* prior art reference against the claims of the present application.

The Applicants also submit that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned person after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of the information disclosure statement.

## STATEMENT OF RELEVANCY

#### WO 02/068582

The teaching of the inventors in the WO 02/068582 publication relates to the development of more stable and nuclease-resistant sequence dependent (or sequence complementary) antisense oligonucleotides that also have a higher affinity to mRNA. As a result, the inventors designed oligonucleotides containing six-membered azasugars (see page 10, lines 17-24 in WO 02/068582). As cited in Table 1 of WO 02/068582, random oligonucleotides containing six-membered azasugars (SEQ ID NOs: 20-24) are disclosed which have strong anti-HIV activity although they had no sequence specificity to HIV-1 gene (see page 46, lines 7-10). Consequently, it is disclosed that the inhibitory effect of oligonucleotides containing six-membered azasugars on HIV-1 replication was not mediated by a sequence specific antisense mechanism against HIV-1 gene, but rather mediated by inhibiting virus attachment on the cell surface (see page 67, lines 22-26). However, one skilled in the art would have construed from this that the antiviral activity seen was due to the six-membered azasugars, the inventors taking such an extensive departure from standard oligonucleotides. Furthermore, regarding the efficacy of the oligonucleotides disclosed in this publication, it is mentioned that these oligonucleotides did not inhibit SIV replication (page 71, lines 1-9) and poliovirus replication (page 72, lines 3-5). Thus, the oligonucleotides taught in the WO 02/068582 reference had no influence on the replication of any other viruses but HIV-1 (as mentioned on page 72, lines 23-25).

## Serial No. 10/661,088

#### *WO 03/097661*

Regarding the WO 03/097661 publication, the Applicants wish to submit that by the nature of the sequences disclosed in this publication, it was concluded that the <u>anti-HIV</u> activity of phosphorothioate oligonucleotides of 37-mer or longer is sequence and structure independent (see page 20, lines 22-24 of WO 03/097661 publication). It is also important to note that all examples disclosed in this publication present <u>in vitro</u> results.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with MPEP § 609.

The Commissioner is hereby authorized to withdraw the fees in the amount of \$180.00 for the submission of an Information Disclosure Statement from Deposit Account No. 19-5113 as well as any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-5113.

Respectfully submitted,

July 23, 2007

Christian Cawthorn, Reg. No. 47,352

Agent of record

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## **OGILVY RENAULT LLP**

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Encl. Form PTO/SB/08A

PTO/SB/08A/B 08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Filing Date	September 12, 2003	<del>JUL.2.4 2007</del>
				First Named Inventor	Andrew Vaillant et al	Ž,
				Art Unit	1648	War way
				Examiner Name	Sharon L. Hurt	PRADEMARIE
Sheet	1	of	1	Attorney Docket Number	16051-10US CC/DBB	/jrl

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number  Number – Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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	No.1	Country Code3 - Number4 - Kind Code5 (if known)		Applicant Of Cited Document		
		WO 02/068582				
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to